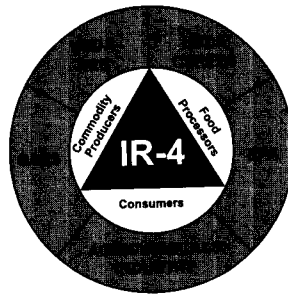


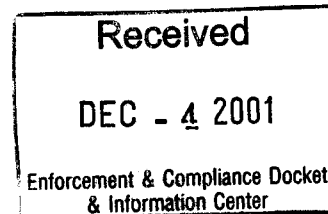
EC-2000-007
IU-D-025



**Interregional Research Project No. 4
Center for Minor Crop Pest Management**

November 28, 2001

US Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460



Dear Sir/Madam:

As the Executive Director of the Interregional Research Project No. 4 (The IR-4 Project), a USDA Cooperative States Research, Extension and Education Service (CSREES) funded research project dedicated to making effective crop pest management solutions available to growers of minor crops, I am pleased to provide comments on the Agency's proposed Cross-Media Electronic Reporting and Record Keeping Rule (CROMERRR) that was published in the Federal Register, 40 CFR Part 3, (Volume 66, Number 170, pages 46161-46195) on August 31, 2001.

The IR-4 Project is a cooperative project comprised of Land Grant University faculty/staff participants and USDA-ARS research scientists whom are conducting GLP residue research projects in support of tolerances for pest management products used by growers of crops deemed as "minor crops". These are crops of less than 300,000 acres in production nationally or crops needing pest management solutions that are deemed "regionally exclusive" and are therefore of non-economic viability to the crop protection industry.

Continued.....

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IR-4 Comments on CROMERRR

There are provisions within CROMERRR that will affect the way the IR-4 Project collects and retains certain kinds of records associated with our GLP research program and we have the following comments and recommendations:

1. Comment :

The IR-4 Project would recommend that at the current time, the electronic record keeping provisions of CROMERRR be separated from the rest of the Rule.

Justification:

The Rule as it is currently written would require the use of undeveloped technology at exorbitant costs. Even after the technology has been developed, it would have to be tested prior to implementation. The majority of the equipment used in analytical laboratories for analysis of chemical samples does not have mechanisms for establishing electronic audit trails or mechanisms for capturing and retaining the metadata associated with these records.

If the Rule is implemented, there would be several issues where clarification or rewording would be useful in creating greater understanding and therefore compliance. They include the following comments.

2. Comment:

According to EPA FIFRA GLP (40 CFR Part 160), there are "other" records that relate to the predicate rule that are required to be maintained, in addition to the GLP data used to generate the final report that is part of a submission to EPA. Examples of these records could include the master schedules listing the status of GLP studies, e-mails used as correspondence concerning GLP studies, temperature and weather records generated by instruments called "Hobo-pods", digital cameras used to photograph field trial plot maps, etc. These "other" records may be a combination of electronic and/or paper records. We recommend that CROMERRR clarify whether these "other" EPA FIFRA GLP (40 CFR Part 160) records are required to be covered and included in CROMERRR.

Justification: It is unclear whether the "other" records required under EPA FIFRA GLP (40 CFR Part 160) are meant to be included as part of CROMERRR. If they are not, they should be listed as an exemption from the Rule.

3. **Comment:** Please suggest alternative options and strategies for small businesses.

Justification: Many smaller test sites and participating University programs performing work under FIFRA GLPs have fewer than five employees associated with their GLP operations. The purchase, use and maintenance of potentially complex and expensive systems may be prohibitive for these small entities to achieve regulatory compliance.

4. **Comment:** Please clarify the Agency's position regarding the application of CROMERRR to "raw" data.

The Agency has stated that the electronic record-keeping side of CROMERRR will apply only if submitters chose to use electronic record-keeping. That is, data could still be captured with current instrumentation which creates, primarily, an electronic file output and, by SOP, defines the raw data as the paper printout of the electronic version. The signed and dated paper copy of the raw data could still be managed under the pre-CROMERRR regulations for maintaining paper raw data. The original electronic file could still be used to process the data into results which would be captured in an electronic or paper report. The results in the report could be audited against the paper raw data to insure that the final results represent the original raw data. The electronic report could then be submitted electronically, when the Agency is ready to receive such, according to criteria in the electronic document submission side of CROMERRR.

The other interpretation is that if the original data capture is electronic and this electronic file is processed electronically with some software application, then under CROMERRR electronic record-keeping provisions of this proposed rule must be followed and submitters will not have the option of defining the raw data as the signed and dated paper copy of both the initial electronic raw data file and any calculated results electronic files.

Therefore, IR-4 requests that this Rule be kept completely voluntary by accepting the potential for the use of "printouts" from computerized systems as original raw data in addition to having the option of retaining these records in their electronic form.

Justification: If the second interpretation is followed, the voluntary aspect of CROMERRR is not optional based on the predicate rules of GLP.

If raw data were to be permitted to be defined as the use of "printouts", very strong precedence is available for its support. The OECD "Application of the Principles of GLP to Computerized Systems", Monograph No. 116, Section 5 indicates "Computerized systems operating in compliance with GLP

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principles may be associated with raw data in a variety of forms, for example, electronic storage media, computer or instrument printouts and microfilm/fiche. It is necessary that raw data are defined for each computerized system".

5. Additional Comment:


After the publishing of the Final Rule in the Federal Record, there will be a short period of time before the Rule becomes effective. However, the actual phase in period necessary to assess current computer data acquisition systems, to develop an implementation strategy after determining the suitability of new systems, and to identify alternative components that will need to be bridged into the old systems will take several years to accomplish. It is therefore recommended that while the effective date of the Rule maybe only months after the publishing of the Rule, that the enforcement of the Rule be mitigated with a phase in allowance of 3 to 5 years.

Justification:

This enforcement phase in period will allow for adequate time to assess acquisition systems and implement well developed and effective cost effective systems.

The IR-4 Project respectfully submits these questions and comments. We look forward to participating in what promises to be a process that results in a Final Rule that meets the Agency's needs for managing and receiving electronic documents and facilitates industry's and academia's ability to comply in a timely fashion.

Sincerely,



Dr. Robert Holm

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cc:

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IR-4 Project Management Committee Members (email)

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